

Claims

We claim:

1. A method for the assessment of glycemic control of a human patient using blood glucose readings comprising the steps of:

(1) obtaining a plurality of blood glucose readings taken within a predetermined time category and time period;

(2) performing first calculations on said readings based on a predetermined normal range of glycemia; and

(3) selecting a pattern label having predetermined criteria by comparing the results of said first calculations to the predetermined pattern label criteria to assess the glycemic control of a human patient.

2. The method of Claim 1 further comprising the steps of:

performing second calculations on said readings based on predetermined thresholds for severe hyperglycemia and severe hypoglycemia; and

if the results of said second calculations meet a severity criteria, selecting and appending a severity suffix having predetermined severity criteria to said pattern label by comparing the results of said second calculations to the severity criteria.

3. The method of Claim 2 further comprising the steps of:

performing third calculations on said readings based on a predetermined normal range of glycemia; and

if the results of said third calculations meet a minor comment criteria, selecting and appending a minor comment having predetermined minor comment criteria to said pattern label by comparing the results of said third calculations to said comment criteria.

4. The method of Claim 1 further comprising the step of outputting said pattern label for said time category as at least part of a glycemic control report.

5. The method of Claim 3 further comprising the step of outputting said pattern label for said time category, including any appended severity suffixes and minor comments, as part or all of a glycemic control report.

6. The method of Claim 1 further comprising the step of repeating method steps (1), (2) and (3) for time categories or time periods other than the predetermined time category and time period.

7. The method of Claim 6 further comprising the step of outputting a pattern label for each time category as part or all of a glycemic control report.

8. The method of Claim 5 further comprising the step of repeating the method steps for time categories or time periods other than the predetermined time category and time period.

9. The method for analyzing blood glucose readings of Claim 1 wherein said pattern label is chosen from a pattern label set comprising at least the following labels and criteria:

	Default Criteria				
Pattern Labels	Minimum No. of Readings	Below Normal %	Above Normal %	Below Normal Mean Cutpoint	Above Normal Mean Cutpoint
Normoglycemia					
1. Excellent Control	10	0	0	NA	NA
2. Optimal Control	14	≤10	≤15	NA	NA
3. Satisfactory Control	14	<20	≤15	NA	NA
Low					
4. Clinically Significant Hypoglycemia	14	≥20- <40	≤15	≤0.8x (lower bound of normoglycemia)	NA

5. Hypoglycemia (Not Clinically Significant)	14	≥ 20 - < 40	≤ 15	$> 0.8x$ (lower bound of normoglycemia)	NA
6. Frequent Clinically Significant Hypoglycemia	14	≥ 40	≤ 15	$\leq 0.8x$ (lower bound of normoglycemia)	NA
7. Frequent Hypoglycemia	14	≥ 40	≤ 15	$> 0.8x$ (lower bound of normoglycemia)	NA
High					
8. Significant Hyperglycemia	14	≤ 10	≥ 15 - < 40	NA	$\geq 1.8x$ (upper bound of normoglycemia)
9. Hyperglycemia	14	≤ 10	≥ 15 - < 40	NA	$< 1.8x$ (upper bound of normoglycemia)
10. Frequent Significant Hyperglycemia	14	≤ 10	≥ 40	NA	$\geq 1.8x$ (upper bound of normoglycemia)
11. Frequent Hyperglycemia	14	≤ 10	≥ 40	NA	$< 1.8x$ (upper bound of normoglycemia)
Fluctuant					
12. Widely Fluctuant	14	≥ 20	≥ 30	NA	NA
13. Fluctuant	14	≥ 10	≥ 10	NA	NA
Other					
14. Insufficient Data	< 14	≥ 0	≥ 0	NA	NA
15. No Available Data	0	NA	NA	NA	NA

10. The method of Claim 2 wherein said severity suffix is selected from the suffix set comprising the following suffixes and criteria:

	Severity Suffix Criteria	
Severity Suffix	# of readings below low threshold	# of readings above high threshold
With isolated severe hypoglycemia	1 – 3	0
With severe hypoglycemia	> 3	0
With isolated severe hyperglycemia	0	1 - 3

With severe hyperglycemia	0	>3
With isolated severe hyperglycemia and isolated severe hypoglycemia	1 – 3	1 - 3
With severe hyperglycemia and severe hypoglycemia	>3	>3

11. The method of Claim 3 wherein said minor comment is selected from the comment set comprising the following comments and criteria:

Pattern Label	Minor comment	Criteria
Normoglycemia		
Excellent Control	None	NA
Optimal Control	With notable hypoglycemia	Below normal mean <0.8x (lower bound of normal range)
	With several readings at the low end of normal	Within normal mean <1.2x (lower bound of normal range)
	With notable hyperglycemia	Above normal mean >1.8x (upper bound of normal range)
Satisfactory Control	With notable hypoglycemia	Below normal mean <0.8 (lower bound of normal range)
	With several readings at the low end of normal	Within normal mean <1.2 (lower bound of normal range)
	With notable hyperglycemia	Above normal mean >1.8x (upper bound of normal range)
Low		
Clinically Significant Hypoglycemia	With notable hyperglycemia	Above normal mean >1.8x (upper bound of normal range)
Hypoglycemia (Not Clinically Significant)	With notable hyperglycemia	Above normal mean >1.8x (upper bound of normal range)
Frequent Clinically Significant Hypoglycemia	With notable hyperglycemia	Above normal mean >1.8x (upper bound of normal range)
Frequent Hypoglycemia	With notable hyperglycemia	Above normal mean >1.8x (upper bound of normal range)
High		
Significant Hyperglycemia	With notable hypoglycemia	Below normal mean <0.8x (lower bound of normal range)
	With several readings at the low end of normal	Within normal mean <1.2x (lower bound of normal range)
Hyperglycemia	With notable hypoglycemia	Below normal mean <0.8x (lower bound of normal range)
	With several readings at the low end of normal	Within normal mean <1.2x (lower bound of normal range)
Frequent Significant Hyperglycemia	With notable hypoglycemia	Below normal mean <0.8x (lower bound of normal range)
	With several readings at the low end of normal	Within normal mean <1.2x (lower bound of normal range)
Frequent Hyperglycemia	With notable hypoglycemia	Below normal mean <0.8x (lower bound of normal range)

	With several readings at the low end of normal	Within normal mean <1.2x (lower bound of normal range)
Fluctuant		
Widely Fluctuant	With a range from (lowest mg/dl to highest mg/dl)	Added to all
Fluctuant	With a range from (lowest mg/dl to highest mg/dl)	Added to all
Other		
Insufficient Data	None	NA
No Available Data	None	NA

12. The method of Claim 1 wherein said first calculations comprise computing:

The number of readings in the time category within the time period;

The percentage of readings within the normal range of glycemia;

The percentage of readings above the normal range of glycemia;

The percentage of readings below the normal range of glycemia;

The mean of readings within the normal range of glycemia;

The mean of readings above the normal range of glycemia; and

The mean of readings below the normal range of glycemia.

13. The method of Claim 2 wherein said second calculations comprise counting the number of readings above a predetermined high glycemia threshold and the number below a low glycemia threshold.

14. The method of Claim 3 wherein said third calculations comprise calculating the mean of readings above normal glycemia, the mean of readings below normal glycemia, and the mean of readings within a normal range of glycemia.

15. The method of analyzing blood glucose readings of Claim 1 wherein the step of performing calculations on said readings further comprises the steps of:

Counting the number of readings in the time category within the time period;

Calculating the quantity of readings above, below and within predetermined normal range of glycemia;

Calculating the mean of readings above, the mean below and the mean within a predetermined normal range of glycemia; and

Calculating the quantity of readings outside predetermined severe glycemia thresholds.

16. A glycemic control report comprising a pattern label for a predetermined time category within a predetermined time period.

17. A glycemic control report comprising a pattern label and severity suffix for a predetermined time category within a predetermined time period.

18. A glycemic control report comprising a pattern label and a minor comment for a predetermined time category within a predetermined time period.

19. A computer system for the assessment of glycemic control using the method of Claim 1.

20. A computer system for the assessment of glycemic control using the method of Claim 2.

21. A computer system for the assessment of glycemic control using the method of Claim 3.

22. A computer system for the assessment of glycemic control using the method of Claim 4.

23. A computer system for the assessment of glycemic control using the method of Claim 5.

24. A computer system for the assessment of glycemic control using the method of Claim 6.

25. A computer system for the assessment of glycemic control using the method of Claim 7.

26. A computer system for the assessment of glycemic control using the method of Claim 8.

27. A computer for creating a glycemic control report of Claim 16.

28. A computer for creating a glycemic control report of Claim 17.

29. A computer for creating a glycemic control report of Claim 18.

30. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 1.

31. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 2.

32. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 3.

33. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 4.

34. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 5.

35. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 6.

36. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 7.

37. A computer-readable medium containing instructions to cause a computer system to perform the method of Claim 8.